

## **Long, Jeff**

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**From:** Long, Jeff  
**Sent:** Wednesday, August 06, 2003 12:07 PM  
**To:** 'ron.gallegos@cusys.edu'; 'alphonse.keasley@colorado.edu'; 'ldickson@uccs.edu'; 'gcoulter@mail.uccs.edu'; 'lgarza-f@carbon.cudenver.edu'; 'xup@spot.colorado.edu'; 'qgonzalez@carbon.cudenver.edu'; 'joann.leclaire@uchsc.edu'; 'robert.winn@uchsc.edu'; 'virginia.sarapura@uchsc.edu'  
**Cc:** 'Lisa Jensen (E-mail)'; 'ken.easterday@uchsc.edu'; Rietmeijer, Kees; 'kathy.self@uchsc.edu'; Moore, Ernest, M.D.; Johnson, Jeff; Haenel, James; Martinez, Dee  
**Subject:** Ethnic Minority Affairs Committee / Clinical Trial  
**Importance:** High

Greetings EMAC members,

I'm writing to make you aware, that Denver Health Medical Center has been selected to be the lead site, as one of twenty Level 1 trauma centers in the United States to participate in an upcoming phase-III clinical trial. This trial involves administering a universally compatible, immediately available oxygen-carrying blood substitute called PolyHeme to trauma patients at the scene of an accident or in an ambulance where blood is currently unavailable, in an effort to increase survival in severely injured and bleeding patients. Since trauma-related injuries are a leading cause of death among Americans under 45 years old, this blood substitute provides an opportunity to treat these patients with an oxygen-carrying solution early, at the scene, which could potentially result in more survivors. In order to carry out this clinical trial, we've requested *an exception from informed consent requirements for emergency research*, in accordance with the Code of Federal Regulations (CFR) § 50.24. As stipulated by this regulation, we must perform community consultation and public disclosure, in an attempt to adequately notify the community about their potential involvement in this trial, and request feedback from citizens.

This study has been approved by the U.S. Food and Drug Administration (FDA). The Colorado Multiple Institutional Review Board (COMIRB), who ultimately has the final local authority to approve this study, has encouraged us to contact you to enlist your assistance in disseminating information and educating the public about their potential inclusion in this possible study (please see quotation below). We've already spoken to well over one hundred people at nine meetings, and have placed multiple public notices in numerous local publications, and have had extensive local and national media coverage. Overall, opinion thus far has been overwhelmingly positive, however concern has been raised by 3 community members, who've felt that we've not adequately targeted minority communities. Please forward us any community groups and their contact people you feel would benefit from participating in our presentation. Please contact Dee Martinez at 303-436-6615, or via e-mail at [dee.martinez@dhha.org](mailto:dee.martinez@dhha.org), and she will arrange for the presentation.

Thank you for your assistance in helping us to disseminate information about this potential life-saving study for the Denver community.

On behalf of Ernest E. "Gene" Moore M.D., Principal Investigator - and the entire study team, best regards.

Jeff

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*"As a part of "Phase 2", the investigators are encouraged to contact the Ethnic Minority Committee at UCHSC and involve them in continuing community presentation of this study, and for help in securing meeting dates with various community groups in and around the Denver area. Thus far, the investigators have had difficulty contacting or securing meeting dates with these organizations. COMIRB, as well as the community members, felt that the Ethnic Minority Committee would be a valuable tool for access to the various community groups. COMIRB also invites the community members to help with the continued process of Community disclosure. COMIRB feels that if the community takes responsibility in the process, and provides their commitment, it will be very valuable to ensure that the public disclosure addresses the issues they are concerned with and the rights of the research subjects are protected."*

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## **Long, Jeff**

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**From:** Long, Jeff  
**Sent:** Monday, July 21, 2003 5:18 PM  
**To:** 'robert.winn@uchsc.edu'  
**Cc:** 'Lisa Jensen (E-mail)'; Moore, Ernest, M.D.; Johnson, Jeff; Martinez, Dee; Haenel, James; Rietmeijer, Kees  
**Subject:** PolyHeme Clinical Trial  
**Importance:** High

Good afternoon Dr. Winn,

I'm writing to follow up on our discussion Friday July 18 with COMIRB.

On behalf of the entire study staff, thank you for your valuable input and offer of support and assistance, in bringing this important clinical trial to fruition. Additionally, I'm hoping that as you offered on Friday you will be able to offer us some direction in terms of whom to contact, in order to arrange necessary meetings to facilitate adequate community consultation, as part of the *exception from informed consent requirements* as outlined in the Code of Federal Regulations.

It is our sincere desire to schedule, and execute these meetings as soon as possible.

Again, thank you.

Best Regards,

Jeff

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**Long, Jeff**

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**From:** Joann.LeClaire@UCHSC.edu  
**To:** Long, Jeff  
**Sent:** Wednesday, August 06, 2003 1:10 PM  
**Subject:** Read: Ethnic Minority Affairs Committee / Clinical Trial

Your message

**To:** Joann.LeClaire@UCHSC.edu  
**Subject:**

was read on 8/6/03 1:10 PM.

**Long, Jeff**

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**From:** Robert.Winn@UCHSC.edu  
**To:** Long, Jeff  
**Sent:** Wednesday, August 06, 2003 1:45 PM  
**Subject:** Read: Ethnic Minority Affairs Committee / Clinical Trial

Your message

**To:** Robert.Winn@UCHSC.edu  
**Subject:**

was read on 8/6/03 1:45 PM.

**Long, Jeff**

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**From:** Virginia.Sarapura@UCHSC.edu  
**To:** Long, Jeff  
**Sent:** Wednesday, August 06, 2003 8:26 PM  
**Subject:** Read: Ethnic Minority Affairs Committee / Clinical Trial

Your message

**To:** Virginia.Sarapura@UCHSC.edu  
**Subject:**

was read on 8/6/03 8:26 PM.

## **Long, Jeff**

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**From:** Ron Gallegos [Ron.Gallegos@cu.edu]  
**To:** Long, Jeff  
**Sent:** Thursday, August 07, 2003 9:42 AM  
**Subject:** Read: Ethnic Minority Affairs Committee / Clinical Trial

Your message

**To:** Ron.Gallegos@cu.edu  
**Subject:**

was read on 8/7/03 9:42 AM.

**Long, Jeff**

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**From:** Garza-Falcon, Leticia [Leticia.Garza-Falcon@cudenver.edu]  
**To:** Long, Jeff  
**Sent:** Thursday, August 14, 2003 9:42 PM  
**Subject:** Not read: Ethnic Minority Affairs Committee / Clinical Trial

Your message

**To:** Leticia.Garza-Falcon@cudenver.edu  
**Subject:**

was deleted without being read on 8/14/03 9:42 PM.